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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/065,278 | 09/30/2002 | Jeffrey C. Leung | 013341.000021 | 5691 |

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MOORE & VAN ALLEN PLLC
P.O. BOX 13706
Research Triangle Park, NC 27709

| EXAMINER | |
|---|---|
| DAWSON, GLENN K | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3731 | |

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/065,278 | LEUNG ET AL. | |
| | Examiner | Art Unit | |
| | Glenn K. Dawson | 3731 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *37-54* is/are withdrawn from consideration.

5)☒ Claim(s) *17-22,34 and 35* is/are allowed.

6)☒ Claim(s) *1-16,23-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

### *Election/Restrictions*

Newly submitted claims 37-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the product as claimed could be used to perform a different method from that claimed, including it could be used in the sewing of fabric.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This action is supplemental to the action mailed out on 04-29-2005. It was mailed to address the status of new claims 37-54 and to indicate the status of newly submitted figures and specification amendments submitted on 01-27-2005. The previous action is hereby vacated and the time period for response will be restarted as of the mailing date of this action.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,5,6,8-16 and 23-33 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative, obvious over Buncke-5931855 (in view of Granger-'911).

Buncke discloses a suture/suture needle combination having the suture swaged to the needle. The suture is bio-absorbable or non-absorbable. The suture has barbs in a staggered or spiral arrangement. The barbs can extend in both directions and since they can be arranged spirally or staggered, some would be 180 degrees offset from others.

The figures show the proximal end of the needle about the same diameter of the suture. However, in the event that neither of these readings of the disclosure is found to adequately disclose the claimed diameter ratio, Granger clearly discloses in col. 7 lines 13-21, that it was known to attach sutures of equal diameter to the suturing needle.

It therefore would have been obvious to have made the suture diameter at least as large as that of the needle, in order to provide a strong suture and one which easily traverses through the tissue.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke-5931855 in view of Granger-'911, as applied to claim1, 5 and 6 above, and further in view of Yuichi-JP 410085225.

Buncke as modified by Granger makes obvious the invention as claimed with the exception of the ratio of needle to suture being about .9-1 or less.

Yuichi discloses that it was known to make the diameter of the needle smaller than the diameter of the suture. It would have been obvious to have attached a suture of

larger diameter than the suturing needle of Buncke as modified by Granger, because such a configuration minimizes bleeding and tissue damage. The examiner contends that the needle being smaller than the suture to a degree worth discussing would meet the limitation of "about .9-1 or less", as this language would include the needle and the suture being about the same size due to the term "about".

Claims 1,2,5,6,12,13,15,23-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-3123077 in view of Granger-'911.

Alcamo discloses a barbed suture having overlapping, spirally arranged, irregularly or regularly spaced about the suture. However, the attachment to a suturing needle and the ratio of the diameters are not disclosed.

Granger discloses in col. 7 lines 13-21, that it was known to attach sutures of equal diameter to the suturing needle It therefore would have been obvious to have made the suture diameter at least as large as that of the needle, in order to provide a strong suture and one which easily traverses through the tissue.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcamo-'077 in view of Granger-'911, as applied to claim1, 5 and 6 above, and further in view of Yuichi-JP 410085225.

Alcamo as modified by Granger makes obvious the invention as claimed with the exception of the ratio of needle to suture being about .9-1 or less.

Yuichi discloses that it was known to make the diameter of the needle smaller than the diameter of the suture. It would have been obvious to have attached a suture of larger diameter than the suturing needle of Alcamo as modified by Granger, because

such a configuration minimizes bleeding and tissue damage. The examiner contends that the needle being smaller than the suture to a degree worth discussing would meet the limitation of "about .9-1 or less", as this language would include the needle and the suture being about the same size due to the term "about".

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger-'911 in view of Alcamo-'077, as applied to the claims above, and further in view of Granger-'013.

Granger as modified by Alcamo makes obvious the invention as claimed with the exception of the coating on the needle. Granger discloses that it was known to place a coating of silicone on a surgical needle. It would have been obvious to have placed a silicone coating on the needle of Leung, as this facilitates the passage of the needle through the tissue.

### *Drawings*

The proposed drawing corrections of 01-27-2005 have been approved by the examiner.

### *Allowable Subject Matter*

Claims 17-22,34 and 35 are allowed.

### *Response to Arguments*

Applicant's arguments filed 01-27-2005 have been fully considered but they are not persuasive.

The examiner did cite 103(a) before the 102/103 rejection of Buncke, or Buncke in view of Granger. The examiner applied Buncke as a possible 102 rejection based on the figures showing a needle about the same diameter as the suture. Clearly if the needle and the suture are of the same diameter, then it would meet the claimed limitation of the ratio of the needle diameter to the suture diameter being 3:1 or less. This limitation covers a range of the needle being smaller than the suture all the way up to and including the needle being 3 times larger than the suture. If the suture and the needle are the same diameter, then the ratio is 1:1, clearly smaller or less than a ratio of 3:1. Therefore, if the figures are correctly showing the suture and the needle being of approximately the same size then the limitation is met. However, absent a finding of the figures properly disclosing the same size of the suture and the needle, Granger clearly discloses that the needle can be of the same size as the suture, again clearly disclosing that it was known to provide a needle having a ratio of its diameter to the suture diameter of 1:1, which is within the claimed ratio range. The teachings of the ratio of the suture needle to the suture would not be limited to sutures without barbs. Therefore whether Buncke alone, or in view of Granger discloses a suture needle the same size as the suture, either case meets the claim limitations. Keeping the needle and suture of the same approximate diameter provides for an atraumatic transition from the end of the needle to the suture.

As sutures require the use of needles, even though Alcamo may not disclose needles, it is clear that the suture disclosed by Alcamo would be at some point attached

to a suturing needle. Granger provides the needle of the claimed size and therefore as pointed out above the claim limitations are met by the combination.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
20 April 2005